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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,275	05/04/2006	Shabtay Dikstein	27241U	3275
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EXAMINER BASQUILL, SEAN M				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
03/18/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/568,275

**Applicant(s)**

DIKSTEIN, SHABTAY

**Examiner**

Sean Basquill

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)  
Paper No(s)/Mail Date 27 Jun 2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Applicants amendments, filed with the response of 19 December 2008, have been acknowledged. Amendments to Claims 22-26 have been entered, as has newly submitted Claim 27.  
Claims 22-27 are presented for examination.

### ***Previous Rejections***

2. Applicants' arguments, filed 19 December 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Priority***

3. Applicant's claim for the benefit of a prior-filed Israeli Application 157535 under 35 U.S.C. 119 is acknowledged. The examiner regrets the oversight of failing to explicitly spell out the acknowledgement of applicant's foreign priority claims vis-à-vis the remaining pending claims when he indicated Claim 24 was unsupported by the disclosure of Israeli Application 157535.

***Claim Rejections - 35 USC § 112 Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 27 recites the limitation "the testosterone phenyl propionate" in Claim 22. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 22 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer in view of Shouls, as put forth in the previous action.

Applicants arguments have been considered and are deemed unpersuasive. While Mazer indeed focuses on the topical application of androgens including testosterone esters "for improving health in women," as cited by the examiner in the previous action, the total disclosure of Mazer is not so generic. Mazer clearly indicates that incorporated within the broad scope of "improving health" are the **restoration, enhancement, and improvement of skin and hair conditions** (C.2, L.63 - C.3, L.5). Given this broad disclosure of utility, the ordinarily skilled artisan would clearly have the motivation to apply the topical androgen preparations for the treatment of atrophy or aging of the skin. Moreover, applicants argument concerning the explicit teaching of the lack of estrogen or derivatives in the disclosure of Mazer, Claim 1 clearly indicates that the only component of the topical therapy which is required is "an androgenic steroid in an amount sufficient to provide a therapeutic effect." To be sure, while other

embodiments of the health improving therapy of Mazer permit therapy with a combination of androgens and estrogens, this particular embodiment clearly requires no such combination. Prior art is art for all that it teaches, not simply isolated preferred embodiments disclosed by prior artisans. MPEP 2123.

Furthermore, Shouls clearly describes, in Table 1, test results of a variety of **topical testosterone patch formulations patch tested on the subject of the case report**, among which were disclosed Sustanon 100 patches. As clearly disclosed in the footnote, the Sustanon 100 patches comprised a mixture of testosterone esters, among which is included testosterone phenylpropionate at a concentration of 40 mg/ml. While the makers of Sustanon may not have received governmental approval to market their drug as a topical therapeutic, that does not prevent individuals from demonstrating it's suitability for such a purpose or of actually employing it as such, as clearly demonstrated by Shouls. Not only does Shouls clearly describe the topical patch formulation relied upon by the examiner in the previous action, but more broadly suggests to the ordinarily skilled artisan the compatibility of formulations commonly used for parenteral treatment in transdermal patch form.

6. Claims 22-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer in view of DeNijis, and Friedman as put forth in the previous action.

Applicants arguments have been considered and are deemed unpersuasive. As discussed above, Mazer contains within the four corners of the disclosure the clear motivation to treat skin disorders using topical preparations of testosterone esters such as testosterone phenylpropionate suggested by DeNijis. In addition, the disclosure of Friedman indicating that pharmaceutically

acceptable carriers such as medium chain triglycerides have utility in the topical delivery of drugs including steroids such as the testosterone esters of Mazer. Given these disclosures along with the technical background of one possessing ordinary skill in the art as evidenced by Shouls, above, the combination of Mazer, DeNijis, and Friedman disclose methods of treating skin disorders using testosterone phenylpropionate with medium chain triglycerides used as the acceptable carrier. As the Supreme Court indicated, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraid v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

7. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer in view of Shouls as applied to Claims 22 and 23, above, and further in view of Friedman as applied to Claims 22-26, above.

Mazer as modified by Shouls, above and in the previous action, discloses the treatment of skin disorders by a topical testosterone phenylpropionate composition, but does not specify the steroid concentration to be used. Friedman, discussed above and in the previous action, discloses topical delivery systems for pharmaceutical compounds such as steroids where the steroid concentration incorporated into the topical composition is between 0.5-5% and medium chain triglycerides are used as the carrier agent.

It would have been *prima facie* obvious to one having ordinary skill in the art to have used the topical delivery system of Friedman in the topical treatment of skin disorders disclosed by Mazer as modified by Shouls. One having ordinary skill in the art would have been motivated to do so because of the recognition by Shouls that injectable formulations may be converted into topical formulations for the delivery of testosterone esters as disclosed by Mazer, and the ordinarily skilled artisan would have recognized the suitability of compositions containing medium chain triglycerides as carriers for topical delivery of steroids as disclosed by Friedman. While the claimed concentration range differs from that suggested by Friedman, the ranges do overlap, leading to a *prima facie* case of obviousness of the claimed ranges. MPEP § 2144.05(I).

### ***Conclusion***

No Claims are allowable.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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